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### Remarks

#### A. Summary of the Invention

The present invention provides an assay device and methods for use of thereof for assaying the sample for the presence or absence of multiple analytes, such as drugs of abuse. The device is composed of a base having adjacent separate slots therein for insertion of one or more analyte test strips each having a test zone and a control zone, one end of which protrudes from each slot, and a cover to retain the test strips within the slot. The device may be used in dipstick or cassette form.

#### B. Claim Amendments

Claims 1-25 were pending prior to the present communication. Claims 21, 23 and 25 have been withdrawn by the Examiner pursuant to Applicant's provisional election of Group I (*i.e.*, claims 1-20, 22 and 24).

Claims 1, 8, 10 and 17 have been amended herein to define Applicants' invention with greater particularity. These amendments add no new matter as they are fully supported by the specification and original claims.

Accordingly, claims 1-20, 22 and 24 are currently under consideration. The present status of all claims in the application is provided in the listing of claims presented herein beginning on page 2.

#### C. Restriction of Claims 1-25

The restriction of claims 1-25 under 35 U.S.C. §§ 121 and 372, as allegedly being drawn to two groups of inventions, is respectfully traversed. However, in order to be fully responsive, Applicant hereby affirms the provisional election of group I (*i.e.*, claims 1-20, 22 and 24) with traverse. Claims 21, 23 and 25 are retained herein pending final disposition of the elected claims.

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D. Double Patenting Rejection of Claims 1-20, 22 and 24

The rejection of claims 1-20, 22 and 24 under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-19 of U.S. Patent No. 6,514,769, is respectfully traversed. Applicants respectfully submit that the present claims are clearly patentably distinct from claims 1-19 of U.S. Patent No. 6,514,769.

Specifically, claims 1-19 of U.S. Patent No. 6,514,76 are directed to a device comprising a sample integrity monitoring system. In contrast, the presently pending claims are directed to a different device which does not contain such a sample integrity monitoring system. Therefore, the present claims are clearly not claiming common subject matter with claims 1-19 of U.S. Patent No. 6,514,76. Accordingly, Applicants respectfully requests reconsideration and withdrawal of this rejection of claims 1-20, 22 and 24.

E. Rejection of Claims 8 and 17 under 35 U.S.C. § 112, second paragraph

The rejection of claims 8 and 17, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention, is respectfully traversed. Applicant respectfully submits that the claims are clear and definite to one of skill in the art.

However, in order to reduce the issues and expedite prosecution, claims 8 and 17 have been amended to recite the two claim dependencies in the alternative. Accordingly, Applicant respectfully requests reconsideration and withdrawal of this rejection of claims 8 and 17.

F. Rejection of claims 1-20, 22 and 24 under 35 U.S.C. § 102(b) – Galloway

The rejection of claims 1-20, 22 and 24 under 35 U.S.C. § 102(b), as allegedly being anticipated by U.S. Patent No. 5,403,551, issued to Galloway *et al.* (hereinafter referred to as “Galloway”), is respectfully traversed.

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Applicant's invention, as defined by claim 1, for example, distinguishes over Galloway by requiring a base and a cover that form the slots for the test strips, which create a device that is completely independent of the sample collection device. In contrast, the device disclosed by Galloway contains a "chromatograph means 40 [that] includes a housing 42 molded into a flat side 44 of the container 12" (see Galloway, at column 4, lines 25-26). Thus, the Galloway device is "an assaying device . . . for both collecting and analyzing a sample" (see Galloway abstract).

Applicant's different design provides significant advantages over the Galloway design. For example, Applicant's test results can be transported or handled conveniently, because they are not attached to the sample collection device.

Therefore, Galloway does not disclose the claimed invention. Accordingly, Applicant respectfully requests reconsideration and withdrawal of this rejection of claims 1-20, 22 and 24.

G. Rejection of claims 1-9, 18 and 22 under 35 U.S.C. § 102(e) – Cipkowski

The rejection of claims 1-9, 18 and 22 under 35 U.S.C. § 102(e), as allegedly being anticipated by U.S. Patent No. 5,976,895, issued to Cipkowski (hereinafter referred to as "Cipkowski"), is respectfully traversed.

Applicant's invention, as defined by claim 1, distinguishes over Cipkowski by requiring slots that are defined in part by raised walls extending upwardly from the floor to separate each adjacent slot from the next. In contrast, the drug test card described by Cipkowski contains test strips that are "recessed in slots in the card so that portions of the test strips project above the test surface 31 as may be seen in Fig. 5" (emphasis added, see Cipkowski, at column 4, lines 5-7 and Fig. 3). According to Cipkowski's design, the test strips are in fluid communication, allowing cross-contamination between test strips.

This problem was specifically addressed by incorporating the slot walls/rails into the design of Applicant's invention. Upon assembly of Applicant's invention, "cover 110 is pressed in place to form an adhesive attachment between cover 110 and the upper edges of rails" (see

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specification, at page 11, lines 10-11). As defined in claim 1, the cover is "attached to the upwardmost surface of each raised wall of the slots of the base", "to separate each adjacent slot from the next". Thus, according to Applicant's design, the test strips are enclosed in separate, individual chambers, preventing any fluid communication or cross-contamination between test strips.

Therefore, Cipkowski does not disclose the claimed invention. Accordingly, Applicant respectfully requests reconsideration and withdrawal of this rejection of claims 1-9, 18 and 22.

H. Rejection of claims 1-4, 7 and 22 under 35 U.S.C. § 102(b) – Janin

The rejection of claims 1-4, 7 and 22 under 35 U.S.C. § 102(b), as allegedly being anticipated by U.S. Patent No. 4,056,359, issued to Janin (hereinafter referred to as "Janin"), is respectfully traversed.

Applicant's invention, as defined by claim 1, distinguishes over Janin by requiring the test strips upon which reagents are disposed on the strip in separate test and control zones. In contrast, Janin requires that reagents are stored (in a chamber of the device or separately), then added to the device as the assay is performed (see Janin, at column 4, lines 5-12).

Further, nothing in the Janin device is present to avoid admixture of reagents across the test slides when present in the "test strip" (in Janin, the phrase "test strip" refers to the entire device, rather than to individual testing matrices within the device; see Janin, at column 3, line 66 through column 4, line 5). Hence, the Janin device cannot be adapted for use with the ubiquitous test strips with which the present invention is to be used.

Moreover, Janin is entirely a "mechanical" device for identifying the presence of *whole cells*; i.e., micro-organisms, in a sample (see Janin, at column 2, line 38 through column 3, line 2).

Therefore, Janin does not disclose the claimed invention. Accordingly, Applicant respectfully requests reconsideration and withdrawal of this rejection of claims 1-4, 7 and 22.

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I. Rejection of claims 1-4, 7 and 22 under 35 U.S.C. § 102(b) – Boger

The rejection of claims 1-4, 7 and 22 under 35 U.S.C. § 102(b), as allegedly being anticipated by U.S. Patent No. 4,518,565, issued to Boger *et al.* (hereinafter referred to as “Boger”), is respectfully traversed.

Applicant’s invention, as defined by claim 1, distinguishes over Boger by requiring a multiplicity of test strips, including both a test zone and a control zone, both of which are visible for side by side comparison through a window within the cover of the inventive test device. The device therefore permits a level of accuracy not obtainable in the Boger device.

In the Boger device, openings through the top member (cover) of the device each correspond “to the location and dimension of the reagent pads on each test device” and are aligned in “perfect registry” therewith, so the openings have the “same number and the same configuration as the reagent pads...” (see Boger, at column 3, lines 28-32; column 3, line 65 through column 4, line 2; and column 4, lines 10-13).

The reason for the alignment is that, in the Boger device, the reagents are disposed on pads which “extend upward” from the surface of the test substrate so as to be “raised to a height substantially above the surface of the substrate...” (see Boger, at column 5, lines 34-40 and Claim 1). The configuration is said to permit automation of assays using the device, while minimizing spillage from one reagent pad to the next (see Boger, at column 5, lines 29-40).

Thus, in the Boger device, the openings through the cover must not be significantly larger in dimensions than the reagent pads. Further, only one reagent is disposed on each pad, such that only one test zone is visible through each opening. As such, either the device must include only reagents pads disposed with the same reagent for use as test zones (thereby precluding the inclusion of a visible control zone or pads with different reagents), or separate openings must be assigned to pads with different reagents (requiring use of the device with customized automated

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handling equipment whose use the Boger invention seeks to avoid; see Boger , e.g., at column 5, lines 12-31).

Furthermore, the presently claimed device is intended for use to detect multiple analytes in a single sample. For the reasons noted above, the Boger device is not well adapted to such a use.

Therefore, Boger does not disclose the claimed invention. Accordingly, Applicant respectfully requests reconsideration and withdrawal of this rejection of claims 1-4, 7 and 22.

#### Conclusion

In view of the above amendments and remarks, prompt and favorable action on all claims is respectfully requested. In the event any matters remain to be resolved in view of this communication, the Examiner is encouraged to call the undersigned so that a prompt disposition of this application can be achieved.

Respectfully submitted,



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